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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,321	09/24/2001	Roy A. Black	016761/0170	8287
22428	7590	12/16/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/057,321	BLACK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kathleen M Kerr	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 63-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>corrections</u> .                      |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on July 1, 2004), Applicants filed a response and amendment received on October 1, 2004. Said amendment amended Claims 64, 66, 68, and 70-76. Thus, Claims 63-76 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. non-Provisional Application Nos. 09/611,722 and 09/244,984 filed on July 6, 2000 and February 4, 1999, respectively, and is also granted the benefit of priority for the U.S. Provisional Application Nos. 60/117,476, 60/135,499, and 60/073,709 filed on January 27, 1999, March 30, 1998, and February 4, 1999, respectively.

### ***Compliance with the Sequence Rules***

3. By virtue of Applicant's amendment to the specification citing a SEQ ID NO for the peptide on page 15, the instant application now fully complies with the sequence rules.

4. A new sequence listing in computer readable form and paper copy was filed on October 1, 2004; said sequence listing contains 10 sequences (the previous listing containing 6 sequences) and has been entered. Said sequence listing is considered not to insert new matter based on the incorporation by reference of Black *et al.* Nature (1997) 325:729-733 which discloses SEQ ID NOs:7 and 8 (SEQ ID NOs:9-10 were present in the instant application as originally filed).

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***Withdrawn - Objections to the Specification***

5. Previous objection to the specification for the amendment filed September 24, 2001 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is withdrawn by virtue of the Examiner's reconsideration.
6. Previous objection to the specification for being confusing with respect to a reference on page 22, line 14, is withdrawn by virtue of Applicant's deleting said reference.

***Maintained - Objections to the Specification***

7. Previous objection to the specification for being unclear in its reference to specific residues in both the TACE sequence and the TNF- $\alpha$  sequence without correlating such reference to a full-length SEQ ID NO is maintained. Applicant argues that the reference to the Black *et al.* sequence is sufficient; however, the Examiner disagrees. Most striking is that Black *et al.* is referred to on page 11, but the confusion begins much earlier on in the specification. Thus, upon its first appearance, this "1-477 fragment" is unclear as to its nature. Moreover, any time specific residues are cited, a SEQ ID NO reference must be included for clarity. To assist Applicant in correcting these defects, the Examiner has attached copies of the pages in need of SEQ ID NOs (from Black *et al.*) for clarity. Correction is required.
8. Previous objection to the specification for being unclear concerning "Asn542" and "Asn452" and Cys478 is maintained (see pages 3, 8, and 24). Applicant notes the typographical error of residue 542, but it has not been amended in the substitute specification. Applicant does not address the issue of Cys478 being confusing. See the Examiner's comments above

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concerning the need for clarity and inclusion of appropriate SEQ ID NOs throughout the specification. Correction is required.

9. Previous objection to the specification for containing references to color figures (Figures 2a-2b) without their inclusion is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that a Petition to consider color drawings in the abandoned parent application 09/611,722 somehow corrects the defect. This is not the case. A Petition to file color drawings must be present in the instant application.

***Withdrawn - Claim Objections***

10. Previous objection to Claim 68 for omitting a conjunction between the two items (i) and (ii). Insertion of an "and" is withdrawn by virtue of Applicant's amendment.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

11. Previous rejection of Claims 67 and 74-76 under 35 U.S.C. § 112, second paragraph, as being indefinite for the additional limitations in Claims 67 and 74 as to the physical limitations they impose on the claimed computerized system is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that "the specification describes the nature of the data structure" and cites incorrect page numbers (30-32). On pages 29-31 of the substitute specification, the exact language of Claim 67 is reiterated without any additional explanation or embodiments; the Examiner has read this language and is still unclear as to the metes and bounds of the added limitations of Claim 67 (hence, the rejection previously

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set forth and maintained herein). The same is true of the limitations of Claim 74. As previously noted,

“The specification provides no embodiments of said limitations so that the Examiner might be able to understand their intent. In fact, no description of the computer system used to model the disclosed crystal structure coordinates of Table 1 is exemplified. In Maskos *et al.* (see IDS), which is Applicant’s journal publication of the disclosed coordinates, an SGI workstation was used with particular programs. It is unclear if SGI stations contain the limitations or if particular programs are required or none-of-the-above. Clarification is required.”

12. Previous rejection of Claims 63-65 under 35 U.S.C. § 112, first paragraph, new matter, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive. Firstly, Applicant argues that the Examiner has not met the burden for a showing of lack of written description in the specification as originally filed. The Examiner disagrees; as noted previously, support for the claimed limitations could not be found in the specification. What more evidence could be provided?

Applicant also argues, using guidelines and case law about written description, that the specification “as a matter of general fact” discloses processors using program codes because the fact that processors use program codes is well known in the art. This argument is not convincing for two reasons. Firstly, the matter is one of new matter (original support in the description), not adequate written description in general (see M.P.E.P. § 608.04). The particular breadth and embodiments of the subject matter added by amendment must be supported in the specification as originally filed - not merely implied by the specification due to a skilled artisan’s knowledge. Moreover, in the instant case, two specific programs are amended into Claim 63, each with specific functionality. These are in no way either explicitly or implicitly supported by the

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specification as originally filed; moreover, the limitations are not inherent limitations such that one of skill in the art would requisitely consider them a part of the disclosure based on the skill in the art since other programs could be included. If these were inherent limitations, they may or may not be considered new matter (see M.P.E.P. § 604.08(a)).

Applicant is required to cite clear support (page and line number) in the originally filed disclosure for the alleged new matter or to cancel said new matter. Review of an Examiner's holding of new matter is by way of appeal when the new matter is in the claims (see M.P.E.P. § 608.04(c)).

13. Previous rejection of Claims 66-76 under 35 U.S.C. § 112, first paragraph, new matter, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Firstly, Applicant argues that the Examiner has not met the burden for a showing of lack of written description in the specification as originally filed. The Examiner disagrees; as noted previously, support for the claimed limitations could not be found in the specification. What more evidence could be provided?

Applicant further argues that the mere assertion that the language is differing is not sufficient. The Examiner disagrees with this assessment of the previous rejection. As stated previously,

"Partial support for Claim 66 can be found in original Claim 26; however, several limitations in the originally filed claim have been removed rendering Claim 66 broader than originally described. Partial support is also on pages 32-33, wherein again the description is of a species and Claim 66 is a genus of said species. Thus, the breadth of Claim 66 is not described

in the specification as originally filed...Also in Claims 66-76, the concept of “multi-dimensional”, as opposed to three-dimensional as originally filed, is considered new matter.”

Thus, it is clear the Examiner did more than not find exact claim language. None of the issues noted above have been specifically address by Applicant in response to the previously set forth rejection.

Applicant is required to cite clear support (page and line number) in the originally filed disclosure for the alleged new matter or to cancel said new matter. Review of an Examiner’s holding of new matter is by way of appeal when the new matter is in the claims (see M.P.E.P. § 608.04(c)).

14. Previous rejection of Claims 63, 65, and 66-76 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that because a single representative species, the crystal structure coordinates of SEQ ID NO:8 as represented in Table 1, is disclosed, wherein said structure depicts the “functional” portion of the molecule, no other species or description of the structure/function relationship is required to satisfy the requirement for adequate written description of a claimed genus. This is not the case. As clearly set forth previously, the instant claims are drawn to a genus of media and systems using any TACE structural data (note the exclusion of Claim 64 in the instant rejection as it is drawn to medium of specific data from Table 1). Said genus is not specifically bounded by a particular structure. Thus, when varying structures are present in the genus, the *Enzo Biochemical* analysis applies wherein a representative number of species is required (which the single data in Table 1 can be representative) and a correlation between structure and function must be set forth. No such



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correlation is required in the claims. In fact, no specific structure is required in the claims. As previously noted,

“The specification teaches the soluble TACE polypeptide from human; the specification also teaches its truncation, mutation, and His-tagging for purification and crystallographic studies of the resultant polypeptide (see page 3, first paragraph). The specification also teaches a particular crystal of said TACE polypeptide and its specific atomic coordinates in Table 1. Does this species adequately describe the claimed genus of any crystallographic structural data of any TACE polypeptide? A single species is disclosed. This single species cannot support description of the entire genus because no correlation between the disclosed species and all TACE polypeptides is described. Moreover, the single species is not of a full-length TACE polypeptide, the structure of which is left wholly undescribed. Therefore, Claims 63 and 65-76, as written, fail to satisfy the written description requirement.”

For all these reasons, the instant rejection is maintained.

***Maintained - Claim Rejections - 35 U.S.C. § 102***

15. Previous rejection of Claims 66-69 and 74-76 under 35 U.S.C. § 102(a) as being anticipated by Cirilli *et al.* is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that since the claims now recite a system using crystallographic data the art no longer applies. The Examiner disagrees. The instant claims are product claims. The data obtained from the x-ray analysis of Cirilli *et al.* is no different from the data obtained by other means - see, in particular, the resolution of the data. Applicant has not set forth reasons as to why crystallographic data “looks” and different than x-ray data when both kinds of data are atomic structure data. Thus, the instant rejection is maintained.

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***Maintained - Claim Rejections - 35 U.S.C. § 103***

16. Previous rejection of Claims 70-73 under 35 U.S.C. § 103(a) as being unpatentable over Cirilli *et al.* (see IDS) is maintained for the reasons cited above under the maintenance of the rejection under 35 U.S.C. § 102(a).

***Conclusion***

17. Claims 63-76 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

December 11, 2004